

CLAIMS

1. A process for production of cation crystals of GH or of GH derivatives, comprising the following steps:
 - a) to a solution of GH or derivatives thereof is added
5 cations of inorganic or organic nature and an organic solvent or a mixture of organic solvents at a pH between 5.0 and 6.8,
 - b) growing of crystals at a temperature from about 0 to about 30°C, and
 - c) isolation of the cation crystals by known means.
- 10 2. A process according to claim 1, wherein the pH in step a) is from 5.8 to 6.5, preferably from 6.0 to 6.5.
3. A process according to claim 1, wherein the organic solvent is selected from the group consisting of short chained aliphatic, cyclic or aromatic alcohols or ketones.
- 15 4. A process according to claim 3, wherein the organic solvent is selected from the group consisting of acetone, methanol, ethanol and 2-propanol.
5. A process according to claim 4, wherein the organic solvent is ethanol or acetone.
- 20 6. A process according to any of claims 1 to 5 wherein the organic solvent is added in a concentration of about 0.1 to about 50% v/v.
7. A process according to claim 6, wherein the organic solvent is added in a concentration of 0.1 to 30%, preferably from 0.1
25 to 20%, more preferred from 5 to 15% and most preferred from 6 to 12%.

8. A process according to any of the preceding claims 1 to 7, wherein the cation is a divalent cation.

9. A process according to claim 8, wherein the divalent cation is Zn^{++} .

5 10. A process according to claim 9, wherein Zn^{++} is added in a concentration below the limit for unspecific precipitation of amorphous material.

11. A process according to claim 10, wherein Zn^{++} is added in a concentration from 0.5 to 10 mol Zn^{++} /mol GH.

10 12. A process according to claim 11 wherein the concentration of Zn^{++} is from 1.0 to 3.0 mol Zn^{++} /mol GH, more preferred from 1.1 to 2.2 mol Zn^{++} /mol GH and most preferred from 1.2 to 2.0 mol Zn^{++} /mol GH.

13. A process according to any of the preceding claims, wherein
15 the growth hormone is hGH or derivatives thereof.

14. A process according to any of the preceding claims, wherein the temperature in step b) is from about 4 to about 25°C.

15. Cation crystals of hGH or hGH derivatives.

16. Crystals according to claim 15, wherein the cation is Zn^{++} .

20 17. Crystals according to claim 16, wherein the molar ratio between Zn^{++} and GH is from about 0.2 to about 10, preferably from about 0.5 to 5 and more preferably from about 0.5 to 2.0.

18. Pharmaceutical preparations, characterized in that they contain crystals according to ~~any~~ of claims 15 to 17.

19. Use of a crystallization process according to claims 1 to 14 as a purification and/or isolation step in the manufacturing of GH.